Medical Policy

Blue Cross Blue Shield Blue Care Network of Michigan

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***Current Policy Effective Date: 9/1/24**
(See policy history boxes for previous effective dates)

Title: Endovascular Therapies For Extracranial Vertebral Artery Disease

Description/Background

VERTEBROBASILAR CIRCULATION ISCHEMIA

Ischemia of the vertebrobasilar or posterior circulation accounts for about 20% of all strokes. Posterior circulation strokes may arise from occlusion of the innominate and subclavian arteries, the extracranial vertebral arteries, or the intracranial vertebral, basilar, or posterior cerebral arteries. Compared with carotid artery disease, relatively little is known about the true prevalence of specific causes of posterior circulation strokes, particularly the prevalence of vertebral artery disease. In a report from a stroke registry, Gulli et al (2013) estimated that, in 9% of cases, posterior circulation strokes are due to stenosis of the proximal vertebral artery.[1] Patients who experience strokes or transient ischemic attacks of the vertebrobasilar circulation face a 25% to 35% risk of stroke within the subsequent 5 years. In particular, the presence of vertebral artery stenosis increases the 90-day risk of recurrent stroke by about 4-fold.

Relevant Clinical Anatomy and Pathophysiology

Large artery disease of the posterior circulation may be due to atherosclerosis (stenosis), embolism, dissection, or aneurysms. In about a third of cases, posterior circulation strokes are due to stenosis of the extracranial vertebral arteries or the intracranial vertebral, basilar, and posterior cerebral arteries. The proximal portion of the vertebral artery in the neck is the most common location of atherosclerotic stenosis in the posterior circulation. Dissection of the extracranial or intracranial vertebral arteries may also cause posterior circulation ischemia. By contrast, posterior cerebral artery ischemic events are more likely to be secondary to embolism from more proximal vessels.

The vertebral artery is divided into 4 segments, V1 though V4, of which segments V1, V2, and V3 are extracranial. V1 originates at the subclavian artery and extends to the C5 or C6 vertebrae; V2 crosses the bony canal of the transverse foramina from C2 to C5; V3 starts as

the artery exits the transverse foramina at C2 and ends as the vessel crosses the dura mater and becomes an intracranial vessel. The most proximal segment (V1) is the most common location for atherosclerotic occlusive disease to occur, while arterial dissections are most likely to involve the extracranial vertebral artery just before the vessel crosses the dura mater. Compared with the carotid circulation, the vertebral artery system is more likely to be associated with anatomic variants, including a unilateral artery.

Atherosclerotic disease of the vertebral artery is associated with conventional risk factors for cerebrovascular disease. However, risk factors and the underlying pathophysiology of vertebral artery dissection and aneurysms differ. Extracranial vertebral artery aneurysms and dissections are most often secondary to trauma, particularly those with excessive rotation, distraction, or flexion/extension, or iatrogenic injury, such as during cervical spine surgeries. Spontaneous vertebral artery dissections are rare, and in many cases are associated with connective tissue disorders, including Ehlers-Danlos syndrome type IV, Marfan syndrome, autosomal dominant polycystic kidney disease, and osteogenesis imperfecta type I.[2]

Management of Extracranial Vertebral Artery Disease

The optimal management of occlusive extracranial vertebral artery disease is not well-defined. Medical treatment with antiplatelet or anticoagulant medications is a mainstay of therapy to reduce stroke risk. Medical therapy also typically involves risk reduction for classical cardiovascular risk factors. However, no randomized trials have compared specific antiplatelet or anticoagulant regimens.

Surgical revascularization may be used for vertebral artery atherosclerotic disease, but open surgical repair is considered technically challenging due to poor access to the vessel origin. Surgical repair may involve vertebral endarterectomy, bypass grafting, or transposition of the vertebral artery, usually to the common or internal carotid artery. Moderately sized, single-center case series of surgical vertebral artery repair from 2012 and 2013 have reported overall survival rates of 91% and 77% at 3 and 6 years postoperatively, respectively, and arterial patency rates of 80% after 1 year of follow-up.[3,4] Surgical revascularization may be used when symptomatic vertebral artery stenosis is not responsive to medical therapy, particularly when bilateral vertebral artery stenosis is present or when unilateral stenosis is present in the presence of an occluded or hypoplastic contralateral vertebral artery. Surgical revascularization may also be considered in patients with concomitant symptomatic carotid and vertebral disease who do not have relief from vertebrobasilar ischemia after carotid revascularization.

The management of extracranial vertebral artery aneurysms or dissections is controversial due to uncertainty about the risk of thromboembolic events associated with aneurysms and dissections. Antiplatelet therapy is typically used; surgical repair, which may include vertebral bypass, external carotid autograft, and vertebral artery transposition to the internal carotid artery, or endovascular treatment with stent placement or coil embolization, may also be used.

Given the technical difficulties related to surgically accessing the extracranial vertebral artery, endovascular therapies have been investigated for extracranial vertebral artery disease. Endovascular therapy may consist of percutaneous transluminal angioplasty, with or without stent implantation.

Regulatory Status

Currently, no endovascular therapies approved by the U.S. Food and Drug Administration (FDA) specifically for the treatment of extracranial vertebral artery disease.

Various stents, approved for use in the carotid or coronary circulation have been used for extracranial vertebral artery disease, which may be self- or balloon-expandable.

Two devices have been approved by FDA through the humanitarian device exemption process for *intracranial* atherosclerotic disease. This form of FDA approval is available for devices used to treat conditions with an incidence of 4000 or less per year; FDA only requires data showing "probable safety and effectiveness." Devices with their labeled indications are as follows:

1. Neurolink System® (Guidant, Santa Clara, CA). "The Neurolink system is indicated for the treatment of patients with recurrent intracranial stroke attributable to atherosclerotic disease refractory to medical therapy in intracranial vessels ranging from 2.5 to 4.5 mm in diameter with ≥50% stenosis and that are accessible to the stent system."

2. Wingspan™ Stent System (Boston Scientific, Fremont, CA). "The Wingspan Stent System with Gateway PTA Balloon Catheter is indicated for use in improving cerebral artery lumen diameter in patients with intracranial atherosclerotic disease, refractory to medical therapy, in intracranial vessels with ≥50% stenosis that are accessible to the system."

Medical Policy Statement

Endovascular therapy, including percutaneous transluminal angioplasty (PTA) with or without stenting, is considered experimental/investigational in the management of extracranial vertebral artery disease. The evidence is insufficient to determine whether endovascular therapy for extracranial vertebral artery stenosis, dissections, aneurysms and arteriovenous fistulae improves health outcomes.

Inclusionary and Exclusionary Guidelines

N/A

CPT/HCPCS Level II Codes *(Note: The inclusion of a code in this list is not a guarantee of coverage. Please refer to the medical policy statement to determine the status of a given procedure.)*

Established codes:

N/A

Other codes (investigational, not medically necessary, etc.):

0075T 0076T

Rationale

Evidence reviews assess the clinical evidence to determine whether the use of a technology improves the net health outcome. Broadly defined, health outcomes are length of life, quality of life, and ability to function, including benefits and harms. Every clinical condition has specific outcomes that are important to patients and to managing the course of that condition. Validated outcome measures are necessary to ascertain whether a condition improves or worsens; and whether the magnitude of that change is clinically significant. The net health outcome is a balance of benefits and harms.

To assess whether the evidence is sufficient to draw conclusions about the net health outcome of a technology, 2 domains are examined: the relevance and the quality and credibility. To be relevant, studies must represent one or more intended clinical use of the technology in the intended population and compare an effective and appropriate alternative at a comparable intensity. For some conditions, the alternative will be supportive care or surveillance. The quality and credibility of the evidence depend on study design and conduct, minimizing bias and confounding that can generate incorrect findings. The randomized controlled trial (RCT) is preferred to assess efficacy; however, in some circumstances, nonrandomized studies may be adequate. RCTs are rarely large enough or long enough to capture less common adverse events and long-term effects. Other types of studies can be used for these purposes and to assess generalizability to broader clinical populations and settings of clinical practice.

Angioplasty With or Without Stenting for Extracranial Vertebral Artery Stenosis

Clinical Context and Therapy Purpose

The purpose of percutaneous transluminal angioplasty with or without stent implantation in individuals who have extracranial vertebral artery stenosis is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The following PICO was used to select literature to inform this review.

Populations

The relevant population of interest is individuals with extracranial vertebral artery stenosis.

Interventions

The therapy being considered is percutaneous transluminal angioplasty with or without stent implantation.

Comparators

The following practice is currently being used to treat extracranial vertebral artery stenosis; medical management with antiplatelet or anticoagulant medications. Medical management

also typically involves risk reduction for classical cardiovascular risk factors. The optimal management of occlusive extracranial vertebral artery disease is not well-defined.

Outcomes

The general outcomes of interest are overall survival, symptoms, morbid events, treatment-related mortality, and treatment-related morbidity.

Study Selection Criteria

Methodologically credible studies were selected using the following principles:

a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews

Several systematic reviews of published studies were published prior to the Vertebral Artery Ischaemia Stenting Trial (VIST)[5] and the Vertebral Artery Stenting Trial (VAST),[6] which are described in the Randomized Controlled Trials section. A meta-analysis of the Stenting and Aggressive Medical Management of Preventing Recurrent stroke in Intracranial Stenosis (SAMMPRIS) trial, VAST, and VIST showed no advantage for stroke prevention compared with medical therapy alone.[7]

Lattanzi et al (2018) conducted a systematic review and meta-analysis of 4 RCTs, including VAST and VIST, of endovascular treatment compared to medical treatment in patients with symptomatic vertebral artery stenosis.[8] Consistent with previous systematic reviews, the researchers found no overall effect of endovascular treatment on any primary or secondary outcome, including any stroke, any vertebrobasilar territory stroke, ischemic stroke, TIA, myocardial infarction, vascular death, and the composite vascular outcome either within or after 30 days.[8]

Xu et al (2022) published a Cochrane review of 3 RCTs that assessed the safety and efficacy of PTA (with or without stenting) combined with medical treatment, compared to medical treatment alone, in individuals with episodes of cerebral ischemia due to vertebral artery stenosis.[28] Two of the 3 RCTs were VIST and VAST, and the third RCT included patients only with intracranial vertebral artery stenosis. Thus, results of the systematic review are not discussed in detail in this evidence review. Consistent with previous systematic reviews, the researchers did not find significant differences in either short- or long-term risks of death, stroke, or TIA between patients who received endovascular treatment plus medical treatment and those who just received medical treatment.

Randomized Controlled Trials

The Vertebral Artery Ischaemia Stenting Trial (VIST) is the largest RCT published to date comparing stenting with medical therapy in patients who had symptomatic vertebral artery disease.[5,9] Enrollment was originally planned for 1302 patients, but was stopped after 182 participants due to slow recruitment and the end of funding. Patients with symptomatic extracranial or intracranial vertebral artery stenosis and vertebrobasilar transient ischemic attack or stroke in the previous 3 months were randomized to vertebral artery stenting plus best medical therapy or best medical therapy alone. Of the 91 patients randomized to stenting, 33% did not undergo the procedure. The primary end point of fatal or nonfatal stroke occurred in 5 patients in the stent group and 12 in the medical management group (hazard ratio, 0.40; 95% confidence interval [CI], 0.14 to 1.13; p=0.08 by intention-to-treat analysis). Although this study found no benefit of stenting, it was underpowered and lacked the precision to exclude a benefit from stenting.

The VAST trial was a multicenter, phase 2 trial that included 115 patients who had transient ischemic attack (TIA) or minor stroke attributed to vertebral artery stenosis.[6] Randomization to stenting plus medical therapy or medical therapy was stratified by center and level of stenosis; 83.5% of patients had extracranial lesions and the rest had intracranial lesions. Stent selection was by surgeon preference. The primary outcome was the composite of vascular death, stroke, or myocardial infarction (MI) within 30 days. Patients were followed yearly by telephone. The median follow-up was 3.0 years (range, 1.3-4.1). Endovascular therapy plus best medical therapy was not superior to best medical therapy alone in this trial. The primary outcome occurred in 3 (5%) of 57 patients (95% CI, 0% to 11%) in the stenting group and 1 (2%) of 58 patients (95% CI, 0% to 5%) in the medical treatment group. During follow-up, the composite primary outcome occurred in 11 (19%) patients in the stenting group and in 10 (17%) patients in the medical therapy group. The periprocedural risk of a major vascular event in the stenting group was 5%.

Noncomparative Studies

A large number of noncomparative studies, most often enrolling few patients, have described outcomes for patients treated with endovascular therapies for extracranial vertebral artery disease. Some of the cohort studies that report on prospectively collected complication and restenosis rates are shown in Table 1.

Table 1. Cohort Studies of Endovascular Treatment of Extracranial Vertebral Artery Stenosis

Study	Study Design	Population	FU	Main Results	ISR Rate
Kikuchi et al (2014)[10]	Retrospective review of prospectively collected data	404 patients from registry treated with endovascular therapy	30 d	Postprocedural morbidity: 2.0% Postprocedural mortality: 0.3%	Not reported
Sun et al (2015)[11]	Retrospective review of prospectively collected data	188 patients with posterior circulation TIA or stroke and mRS score ≤2	16.5 mo[a]	Technical success rate: 100% 34 patients had recurrent TIA after 30 d No cases of stroke or death occurred	21.2%
Mohammadian et al (2013)[12]	Prospective interventional study	206 patients with clinical signs of vertebral occlusion (239 treated lesions, 202 extracranial)	13.15 mo[a]	Technical success rate: 100%. 89.2% were balloon-expandable bare-metal stents Periprocedural complication rate: 7.2% Complications during FU: overall 6.3%	15.9%
Hatano et al (2011)[13]	Retrospective review of prospectively collected data	117 patients (108 symptomatic, 9 asymptomatic)	48 mo[a]	Technical success rate: 99% During FU, 5 patients had posterior circulation ischemia, 1 had cerebellar infarction with ISR, 2 had posterior circulation strokes without ISR	9.6% at 6 mo

FU: follow-up; ISR: in-stent restenosis; mRS: modified Rankin Scale; TIA: transient ischemic attack.
[a] Mean value.

Section Summary: Angioplasty With or Without Stenting for Extracranial Vertebral Artery Stenosis

The evidence on the overall efficacy of endovascular therapies for extracranial vertebral artery stenosis includes phase 3 and phase 2 RCT (VIST and VAST) that compared endovascular therapy to best medical therapy alone for vertebral artery stenosis. These trials found no advantage of endovascular intervention over best medical therapy alone, with a periprocedural adverse event rate of 5% for the invasive procedures in the VAST trial. Evidence from noncomparative studies has indicated that vertebral artery stenting can be performed with high rates of technical success and low periprocedural morbidity and mortality, and that vessel patency can be achieved in a high percentage of cases. However, long-term follow-up has demonstrated high rates of in-stent stenosis.

Angioplasty With Stenting for Extracranial Vertebral Artery Aneurysms, Dissections, or Arteriovenous Fistula(e)

Clinical Context and Therapy Purpose

The purpose of percutaneous transluminal angioplasty with stent implantation in individuals who have extracranial vertebral artery aneurysms, dissections, or arteriovenous (AV) fistula(e)is to provide a treatment option that is an alternative to or an improvement on existing therapies.

The question addressed in this evidence review is: Does percutaneous transluminal angioplasty with stent implantation improve the net health outcome in patients with extracranial vertebral artery aneurysms, dissections, and arteriovenous fistula(e)?

The following PICO was used to select literature to inform this review.

Populations
The relevant population of interest is individuals with extracranial vertebral artery aneurysms, dissections, or arteriovenous fistula(e).

Interventions
The therapy being considered is percutaneous transluminal angioplasty with stent implantation.

Comparators
The following practice is currently being used to treat extracranial vertebral artery aneurysms, dissections, or AV fistula(e): continued clinical observation, medical management and surgical treatment. The management of extracranial vertebral artery aneurysms or dissections is controversial due to uncertainty about the risk of thromboembolic events associated with aneurysms and dissections. Antiplatelet therapy is typically used; surgical repair, which may include vertebral bypass, external carotid autograft, and vertebral artery transposition to the internal carotid artery, or endovascular treatment with stent placement or coil embolization, may also be used.

Outcomes
The general outcomes of interest are overall survival, symptoms, morbid events, treatment-related mortality, and treatment-related morbidity.

Study Selection Criteria
Methodologically credible studies were selected using the following principles:
a. To assess efficacy outcomes, comparative controlled prospective trials were sought, with a preference for RCTs;
b. In the absence of such trials, comparative observational studies were sought, with a preference for prospective studies.
c. To assess longer term outcomes and adverse events, single-arm studies that capture longer periods of follow-up and/or larger populations were sought.
d. Studies with duplicative or overlapping populations were excluded.

Review of Evidence

Systematic Reviews
Pham et al (2011) conducted a systematic review of studies evaluating endovascular stenting for extracranial carotid and vertebral artery dissections. Eight studies of extracranial vertebral artery stenting with 10 patients (12 vessels) were included.[14] Of the 10 patients included, 70% had associated pseudoaneurysms and 20% had bilateral lesions. Most dissections (60%) were traumatic in etiology, while 20% were spontaneous and 20% were iatrogenic. The indications for stenting were failure of medical management in 40% (defined as a new ischemic event, progression of initial symptoms, or demonstration of an enlarging pseudoaneurysm despite adequate anticoagulation or antiplatelet treatment), contraindication to anticoagulation in 20%, and/or severity of dissection hemodynamics in 60%. No stent-related complications or mortalities were reported in any study. One dissection-related death was reported, although stenting was considered technically successful.

Case Series and Case Reports

Badve et al (2014) retrospectively compared the clinical characteristics of patients with vertebrobasilar dissections with and without aneurysmal dissection treated at a single institution from 2002 to 2010.[15] Thirty patients were identified, 7 with aneurysmal dissections (1 of which was extracranial) and 23 with nonaneurysmal dissections (10 of which were extracranial, and12 of which were combined intracranial/extracranial). Patients were treated with antiplatelet agents (aspirin or clopidogrel; n=8), anticoagulation with warfarin (n=13), or neurointerventional procedures (n=6). One patient in the nonaneurysmal dissection group treated with aspirin died. Kondo et al (2021) retrospectively reviewed patients who had an acute ischemic stroke and received urgent endovascular reperfusion therapy between 2017 and 2019.[16] Three patients with strokes caused by vertebral artery dissection were identified. Dissections at the V3, V4, and extensions of V3 to V4 segments were seen in 1 patient each. Endovascular reperfusion thrombectomy without stenting, stenting alone, and a combination of thrombectomy and stenting were performed in the 3 patients, respectively. In all 3 patients, effective recanalization and functional independence based on modified Rankin scores (scores Oto 2 at 90 days after onset) were achieved.

The use of endovascular therapy for extracranial vertebral artery aneurysms and AV fistulae is similarly limited to small case series and reports. In an early report, Horowitz et al (1996) described a left-sided vertebral artery pseudoaneurysm with dissection between the vessel media and adventitia at the C7 vertebra that was treated with a balloon-expandable stent.[17] Follow-up angiography three months postprocedure showed no filling of the pseudoaneurysm and normal patency of the parent artery. Felber et al (2004) reported on outcomes from endovascular treatment with stent grafts of 11 patients who had aneurysms or AV fistulae of craniocervical arteries, 2 of whom were treated for extracranial vertebral artery disorders with coronary stents (1 aneurysm, 1 traumatic AV fistula).[18] The procedure was technically successful in both subjects, without complications. At follow-up (5 years and 14 months postprocedure in the aneurysm and fistula patients, respectively), the target vessel was patent without stenosis. Herrera et al (2008) reported on outcomes for a single-center series of 18 traumatic vertebral artery injuries, including 16 AV fistulae (7 of which had an associated pseudoaneurysm) and 2 isolated pseudoaneurysms, treated with endovascular therapy.[19] Endovascular therapy consisted of balloon occlusion of the parent vessel and AV fistula in 12 (66.6%) patients, coil embolization in 2 (11.1%) patients, and detachable balloon and coil embolization, balloon occlusion, and stent delivery with coil and *n*-butyl cyanoacrylate embolization of a AV fistulae each in 1 (5.5% each) patient. Angiography immediately after endovascular treatment demonstrated complete occlusion in 16 (88.9%) patients and partial occlusion in 2 (11.1%) patients. Seventeen (94.5%) patients had complete resolution of symptoms.

Other case reports have described successful use of endovascular treatment with stenting for iatrogenic vertebral artery pseudoaneurysms,[20] iatrogenic vertebral artery AV fistula,[21] extracranial vertebral artery aneurysm with an unknown cause,[22] and extracranial vertebral artery aneurysm with a cervical vertebral AV fistula.[23]

Section Summary: Angioplasty With Stenting for Extracranial Vertebral Artery Aneurysms, Dissections, or Arteriovenous Fistula(e)
The evidence on use of endovascular therapies for the treatment of extracranial vertebral artery dissections, aneurysms, or AV fistulae consists of small case series and case reports. The available reports and series have indicated that endovascular therapy for extracranial vertebral artery disorders other than stenosis is feasible and may be associated with favorable outcomes. However, given the lack of evidence comparing endovascular therapies to alternatives, the evidence is insufficient to determine whether endovascular therapy for extracranial vertebral artery dissections, aneurysms, or AV fistula€ versus existing alternative therapies.

SUMMARY OF EVIDENCE

For individuals who have extracranial vertebral artery stenosis who receive percutaneous transluminal angioplasty (PTA) with or without stent implantation, the evidence includes randomized controlled trials (RCTs) and noncomparative studies. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. Two RCTs, the Vertebral Artery Ischaemia Stenting Trial (VIST) and the Vertebral Artery Stenting Trial (VAST), found no advantage for endovascular intervention compared with best medical therapy alone. Evidence from noncomparative studies has shown that vertebral artery stenting can be performed with high rates of technical success and low periprocedural morbidity and mortality, and that vessel patency can be achieved in a high percentage of cases. However, long-term follow-up has demonstrated high rates of in-stent stenosis. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have extracranial vertebral artery aneurysm(s), dissection(s), or AV fistula(e) who receive PTA with stent implantation, the evidence includes small case series and reports. Relevant outcomes are overall survival, symptoms, morbid events, and treatment-related mortality and morbidity. The available evidence has indicated that endovascular therapy for extracranial vertebral artery disorders other than stenosis is feasible and may be associated with favorable outcomes. However, given the lack of data comparing endovascular therapies to alternatives, the evidence is insufficient to permit conclusions about the efficacy of endovascular therapy for extracranial vertebral artery aneurysms, dissections, or AV fistulae. The evidence is insufficient to determine the effects of the technology on health outcomes.

SUPPLEMENTAL INFORMATION

Practice Guidelines and Position Statements

Guidelines or position statements will be considered for inclusion in ‘Supplemental Information’ if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

American Heart Association and American Stroke Association

The American Heart Association and American Stroke Association (2014) issued joint guidelines on prevention of stroke in patients with stroke and transient ischemic attack, which make the following recommendations about treatment of extracranial vertebrobasilar disease.[24] These guidelines were updated in 2021 and the most recent recommendations and evidence statements about treatment of extracranial vertebrobasilar disease are listed in Table 2.[25]

Table 2. Guidelines on Stroke Prevention in Patients With Stroke and Transient Ischemic Attack

Recommendation	COR	LOE
"In patients with recently symptomatic extracranial vertebral artery stenosis, intensive medical therapy (antiplatelet therapy, lipid lowering, BP control) is recommended to reduce stroke risk"	I	A
"In patients with ischemic stroke or TIA and extracranial vertebral artery stenosis who are having symptoms despite optimal medical treatment, the usefulness of stenting is not well established"	IIb	B-R
"In patients with ischemic stroke or TIA and extracranial vertebral artery stenosis who are having symptoms despite optimal medical treatment, the usefulness of open surgical procedures, including vertebral endarterectomy and vertebral artery transposition, is not well established"	IIb	C-EO

BP: blood pressure; COR: class of recommendation; LOE: level of evidence; TIA: transient ischemic attack.
Level of Evidence: A: high-quality evidence from more than 1 RCT; B-R: moderate quality of evidence from 1 or more randomized controlled trials; C-EO: consensus of expert opinion based on clinical experience.

American Stroke Association et al

In 2011, a multisociety task force issued guidelines on the management of extracranial vertebral and carotid artery disease which made the following statement about catheter-based revascularization of extracranial vertebral artery disease: “Although angioplasty and stenting of the vertebral vessels are technically feasible, as for high-risk patients with carotid disease, there is insufficient evidence from randomized trials to demonstrate that endovascular management is superior to best medical management.”[26] No specific recommendations are made about endovascular therapies.

U.S. PREVENTIVE SERVICES TASK FORCE RECOMMENDATIONS

Not applicable.

ONGOING AND UNPUBLISHED CLINICAL TRIALS

A search of ClinicalTrials.gov in April 2022 did not identify any ongoing or unpublished trials that would likely influence this review.

Government Regulations

National:

CMS National Coverage Determination (NCD) for Percutaneous Transluminal Angioplasty (PTA) (20.7)
Effective date 10/11/2023, Implementation date 5/13/2024 (27)

Indications and Limitations of Coverage
A. General

This procedure involves inserting a balloon catheter into a narrow or occluded blood vessel to recanalize and dilate the vessel by inflating the balloon. The objective of percutaneous transluminal angioplasty (PTA) is to improve the blood flow through the diseased segment of a vessel so that vessel patency is increased and embolization is decreased. With the development and use of balloon angioplasty for treatment of atherosclerotic and other vascular stenoses, PTA with and without the placement of a stent) is a widely used technique for dilating lesions of peripheral, renal, and coronary arteries.

B. Nationally Covered Indications

The PTA is covered when used under the following conditions:

1. Treatment of Atherosclerotic Obstructive Lesions

-In the lower extremities, i.e., the iliac, femoral, and popliteal arteries, or in the upper extremities, i.e., the innominate, subclavian, axillary, and brachial arteries. The upper extremities do not include head or neck vessels.

-Of a single coronary artery for patients for whom the likely alternative treatment is coronary bypass surgery and who exhibit the following characteristics:

- Angina refractory to optimal medical management;
- Objective evidence of myocardial ischemia; and
- Lesions amenable to angioplasty

-Of the renal arteries for patients in whom there is an inadequate response to a thorough medical management of symptoms and for whom surgery is the likely alternative. PTA for this group of patients is an alternative to surgery, not simply an addition to medical management.

-Of arteriovenous dialysis fistulas and grafts when performed through either a venous or arterial approach.

2. Concurrent with Carotid Stent Placement in Food and Drug Administration (FDA)-Approved Category B Investigational Device Exemption (IDE) Clinical Trials

Effective July 1, 2001, Medicare covers PTA of the carotid artery concurrent with carotid stent placement when furnished in accordance with the FDA-approved protocols governing Category B IDE clinical trials. PTA of the carotid artery, when provided solely for the purpose of carotid artery dilation concurrent with carotid stent placement, is considered to be a reasonable and necessary service when provided in the context of such a clinical trial.

3. Concurrent with Carotid Stent Placement in FDA-Approved Post-Approval Studies

Effective October 12, 2004, Medicare covers PTA of the carotid artery concurrent with the placement of an FDA-approved carotid stent and an FDA-approved or –cleared embolic protection device (effective December 9, 2009) for an FDA-approved indication when furnished in accordance with FDA-approved protocols governing post-approval studies. The Centers for

Medicare & Medicaid Services (CMS) determines that coverage of PTA of the carotid artery is reasonable and necessary in these circumstances.

Local:

Wisconsin Physicians Service Insurance Corporation
Local Coverage Determination (LCD) Category III Codes (L35490) Original effective date 10/1/2015; Revision effective date 3/28/2024

0075T, 0076T Refer to CMS publication 100-03, Medicare National Coverage Determinations (NCD) Manual, Chapter 1– Coverage Determinations, Part 1, § 20.7– Percutaneous Transluminal Angioplasty (PTA). Billing instructions are listed in the CMS Publication 100-04, Medicare Claims Processing Manual, Chapter 32 – Billing Requirements for Special Services, Sections 160-160.3 – PTA for Implanting the Carotid Stent. As directed in The CPT 2018 Professional code book, use 0076T in conjunction with 0075T.

(The above Medicare information is current as of the review date for this policy. However, the coverage issues and policies maintained by the Centers for Medicare & Medicare Services [CMS, formerly HCFA] are updated and/or revised periodically. Therefore, the most current CMS information may not be contained in this document. For the most current information, the reader should contact an official Medicare source.)

Related Policies

Endovascular Procedures for Intracranial Arterial Disease
Extracranial Carotid Angioplasty/Stenting

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The articles reviewed in this research include those obtained in an Internet based literature search for relevant medical references through May 3, 2024, the date the research was completed.

Joint BCBSM/BCN Medical Policy History

Policy Effective Date	BCBSM Signature Date	BCN Signature Date	Comments
10/1/16	6/21/16	6/21/16	Joint policy established
9/1/17	6/20/17	6/20/17	Routine maintenance
9/1/18	6/19/18	6/19/18	Routine maintenance
9/1/19	6/18/19		Routine maintenance
9/1/20	6/16/20		Routine maintenance
9/1/21	6/15/21		Routine maintenance
9/1/22	6/21/22		Routine maintenance
9/1/23	6/13/23		Routine maintenance Vendor: N/A (ky)
9/1/24	6/11/24		Routine maintenance Vendor: N/A (ky)

Next Review Date: 2nd Qtr, 2025

BLUE CARE NETWORK BENEFIT COVERAGE
POLICY: ENDOVASCULAR THERAPIES FOR EXTRACRANIAL VERTEBRAL ARTERY DISEASE

I. Coverage Determination:

Commercial HMO (includes Self-Funded groups unless otherwise specified)	Not covered.
BCNA (Medicare Advantage)	See Government Regulations section of policy.
BCN65 (Medicare Complementary)	Coinsurance covered if primary Medicare covers the service.

II. Administrative Guidelines:

- The member's contract must be active at the time the service is rendered.
- Coverage is based on each member's certificate and is not guaranteed. Please consult the individual member's certificate for details. Additional information regarding coverage or benefits may also be obtained through customer or provider inquiry services at BCN.
- The service must be authorized by the member's PCP except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Services must be performed by a BCN-contracted provider, if available, except for Self-Referral Option (SRO) members seeking Tier 2 coverage.
- Payment is based on BCN payment rules, individual certificate and certificate riders.
- Appropriate copayments will apply. Refer to certificate and applicable riders for detailed information.
- CPT - HCPCS codes are used for descriptive purposes only and are not a guarantee of coverage.